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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,863	03/31/2004	Edward Vaquero	P03166	5586
23702 7590 02/12/2009 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701				
EXAMINER				
LANG, AMY T				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
02/12/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/813,863

**Applicant(s)**

VAQUERO, EDWARD

**Examiner**

AMY T. LANG

**Art Unit**

3731

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6-13 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-13 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The Final Rejection mailed 11/13/2008 is withdrawn since the rejection of Clark does not meet all the claimed requirements.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 3, 4, 6-13, and 22-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 6,491,697 B1) in view of Smith et al. (US 4,934,363).

With regard to **claims 1, 7, and 23**, Clark discloses a device for injecting a foldable IOL into an eye comprising a body (22), an opening to receive an IOL (38), and a lumen (107) through cannula (28) (column 3, lines 62-64; column 6, lines 1-4). The opening (38) forms a loading bay for the IOL. As shown in Figure 1, the lumen comprises a proximal end and an open tip (119). Clark further teaches wherein the

cannula (28) comprises a proximal taper to compress the IOL (column 5, lines 58-63). As shown in Figure 1, this taper is immediately adjacent to and distal to the distal end of the loading bay. Adjacent is defined as close or near to, so the taper is immediately near the distal end of the loading bay.

Clark further teaches wherein slits (121, 111) in the lumen allow the IOL to laterally expand before the IOL is released from the distal tip (column 6, lines 31-40; Figure 7). However, as shown in Figure 5, the slits do not provide wherein the IOL is maintained entirely within the device prior to release.

Smith also teaches a device for injecting a foldable IOL into a patient's eye (column 1, lines 5-9). As shown in Figure 3, the distal end of the device forms a holder, paddle (22). When the IOL is placed within the paddle, the IOL has laterally expanded before it is released from the distal tip of the device (Figures 4 and 5; column 6, lines 12-14, 24-27, and 35-39). Therefore, Smith discloses a distal tip that holds the entire laterally expanded IOL. This advantageously protects the IOL prior to insertion since the edges of the IOL are not vulnerable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the distal tip of Clark to also comprise a holder that can hold the entire laterally expanded IOL. This would allow the sides (18a, 18b) of the IOL optic of Clark to be secured within the device prior to delivery.

As shown in Figure 5 of Clark, the paddle (22) forms a lumen that is larger than the lumen through tube (14). The lumen of paddle (22) must be sufficiently large to hold the entire IOL device in an unfolded state. Since Clark comprises a taper adjacent to

the loading bay and the paddle lumen of Smith is larger than the tube lumen, a distal holder on Clark would therefore comprise a larger lumen than the lumen of the taper to fit the entire IOL in an unfolded state. Therefore, Clark in view of Smith would form an inner lumen that comprises an inner diameter at a location immediately adjacent and distal to the loading bay smaller than the inner diameter at the distal open tip.

With regard to **claims 3 and 22**, Clark further discloses a compressor drawer (40) comprising a leading edge (62) (column 4, lines 12-15). The compressor drawer moves from an open to a closed position to engage and compress the IOL (column 4, lines 28-40).

With regard to **claims 4 and 24**, the device also comprises a plunger (column 3, lines 50-54).

With regard to **claim 6**, as shown in Figure 1, the device has an outer diameter that is substantially constant from the opening (38) to the open tip (119) since “substantially” is not narrowly defined.

With regard to **claims 8, 10, and 12**, as shown in Figures 1-3 of Clark, the region of increase is gradual.

With regard to **claims 9, 11, and 13**, Clark does not teach wherein inner lumen increase in diameter is stepped. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the increase of the inner lumen to a stepped increase because Applicant has not disclosed the modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have

expected Applicant's invention to perform equally well with a gradual increase, as disclosed by Clark, because the lumen is able to receive an IOL lens. Therefore, it would have been an obvious matter of design choice to modify Clark to obtain the invention as specified in the claims.

With regard to **claim 25**, it is the examiner's position that the compressor of Clark overlaps the instantly claimed compressor drawer.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1, 3, 4, 6-13, and 22-25 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

02/09/2009  
/Amy T Lang/  
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731